"Express Mail" Label No. EL 769976426
Date of Deposit May 31, 2001

PATENT
Attorney Docket No.: 15542-000550US

I hereby certify that this is being deposited with the United States Postal Service "Express Mail Post Office to Address" service under 37 CFR 1.10 on the date indicated above and is addressed to:

Assistant Commissioner for Patents
Washington, D.C. 20231

By: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Examiner: Unassigned
GREEN *et al.*	Art Unit: Unassigned
Application No.: Unassigned	PRELIMINARY AMENDMENT
Filed: Herewith	
For: PHARMACEUTICAL LYSINE-CONTAINING POLYPEPTIDE COMPOSITIONS AND METHODS OF USE THEREOF	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination of the above-referenced application, please enter the following amendments and remarks.

A version of the claims with markings to show changes to the claims are provided in Appendix A. All of the pending claims are provided in Appendix B for the Examiner's convenience. Please amend the claims as follows:

IN THE CLAIMS:

Please cancel claims 1-30, without prejudice or disclaimer.

Please add new claims 31-47:

31. A method for augmenting vaccinations in a host comprising:

administering to said host a peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof,

wherein Glx is Glu or Gln; R' is H- or a first amino acid sequence having 7 or fewer amino acids;

wherein R" is –H or a second amino acid sequence having fewer than 7 amino acids;

wherein said peptide has a sequence of at least 2 but not more than 9 amino acids; and

administering to said host a vaccine.

32. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered simultaneously with said vaccine.

33. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered prior to the administration of said vaccine.

34. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered after the administration of said vaccine.

35. The method of claim 31, wherein R' is H-, Glx-, Thr-Ala-Glx-, Thr-Pro-Glx-, Ser-Ala-Glx-, Ser-Pro-Glx-, Ser-Ser-Glx-, Met-Leu-Thr-Ala-Glx-, or Leu-Thr-Ala-Glx-; and R" is -H, -Ala, -Ala-Ala or -Ala-Val.

36. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is selected from the group consisting of: Thr-Ala-Glu-Glu-Lys, Thr-Ala-Gln-Gln-Lys, and Glu-Lys.

37. The method of claim 31, wherein R" is -H.

38. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is selected from the group consisting of: Thr-Pro-Glu-Glu-Lys, Thr-Pro-Gln-Gln-Lys, and Thr-Pro-Glx-Glx-Lys.

39. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is selected from the group consisting of: Leu-Thr-Ala-Glx-Glx-Lys-Ala, Leu-Thr-Ala-Glx-Glx-Lys-Ala-Ala, and Leu-Thr-Ala-Glx-Glx-Lys-Ala-Val.

40. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered as a pharmaceutical composition.

41. The method of claim 40, wherein said pharmaceutical composition comprises said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof in an amount of 0.001% to 20% by weight and a pharmaceutically acceptable carrier.

42. The method of claim 41, wherein said pharmaceutically acceptable carrier is an aqueous solution.

43. The method of claim 41, wherein said pharmaceutically acceptable carrier comprises a buffer selected from sodium acetate, sodium lactate, sodium chloride, potassium chloride and calcium chloride.

44. The method of claim 41, wherein said pharmaceutical composition comprises 0.1 mg of the peptide.

45. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered parenterally.

46. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered orally.

47. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered intranasally, intravenously or intramuscularly.

REMARKS

Status of the Claims

Claims 1-30 were pending in this application. The Applicants have canceled claims 1-30, and have added claims 31-47, which are set forth in the Appendix for the Examiner's convenience. These claims do not add any new matter and find support in the application at, inter alia, page 7, lines 27-33; page 34, line 1, bridging to page 47, line 35; and page 52, lines 1-8. Therefore, claims 31-47 are currently pending and are presented for examination.

Priority Information of the case

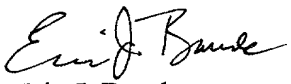
The present application is a divisional application of U.S. Patent Application 09/368,449, which is a divisional application of U.S. Patent Application No. 08/484,511 (which issued as U.S. Patent No. 6,100,380), which is a continuation-in-part application of U.S. Patent Application No. 08/144,779 (which issued as U.S. Patent No. 6,066,622).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Eric J. Baude
Reg. No. 47,413

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
EJB
SF 1213239 v1

APPENDIX A
VERSION WITH MARKINGS TO SHOW CHANGES

31. A method for augmenting vaccinations in a host comprising:

administering to said host a peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof,

wherein Glx is Glu or Gln; R' is H- or a first amino acid sequence having 7 or fewer amino acids;

wherein R" is –H or a second amino acid sequence having fewer than 7 amino acids;

wherein said peptide has a sequence of at least 2 but not more than 9 amino acids; and

administering to said host a vaccine.

32. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered simultaneously with said vaccine.

33. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered prior to the administration of said vaccine.

34. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered after the administration of said vaccine.

35. The method of claim 31, wherein R' is H-, Glx-, Thr-Ala-Glx-, Thr-Pro-Glx-, Ser-Ala-Glx-, Ser-Pro-Glx-, Ser-Ser-Glx-, Met-Leu-Thr-Ala-Glx-, or Leu-Thr-Ala-Glx-; and R" is -H, -Ala, -Ala-Ala or -Ala-Val.

36. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is selected from the group consisting of: Thr-Ala-Glu-Glu-Lys, Thr-Ala-Gln-Gln-Lys, and Glu-Lys.

37. The method of claim 31, wherein R" is -H.

38. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is selected from the group consisting of: Thr-Pro-Glu-Glu-Lys, Thr-Pro-Gln-Gln-Lys, and Thr-Pro-Glx-Glx-Lys.

39. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is selected from the group consisting of: Leu-Thr-Ala-Glx-Glx-Lys-Ala, Leu-Thr-Ala-Glx-Glx-Lys-Ala-Ala, and Leu-Thr-Ala-Glx-Glx-Lys-Ala-Val.

40. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered as a pharmaceutical composition.

41. The method of claim 40, wherein said pharmaceutical composition comprises said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof in an amount of 0.001% to 20% by weight and a pharmaceutically acceptable carrier.

42. The method of claim 41, wherein said pharmaceutically acceptable carrier is an aqueous solution.

43. The method of claim 41, wherein said pharmaceutically acceptable carrier comprises a buffer selected from sodium acetate, sodium lactate, sodium chloride, potassium chloride and calcium chloride.

44. The method of claim 41, wherein said pharmaceutical composition comprises 0.1 mg of the peptide.

45. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered parenterally.

46. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered orally.

47. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered intranasally, intravenously or intramuscularly.

APPENDIX B
PENDING CLAIMS SUBJECT TO EXAMINATION

31. A method for augmenting vaccinations in a host comprising:

administering to said host a peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof,

wherein Glx is Glu or Gln; R' is H- or a first amino acid sequence having 7 or fewer amino acids;

wherein R" is –H or a second amino acid sequence having fewer than 7 amino acids;

wherein said peptide has a sequence of at least 2 but not more than 9 amino acids; and

administering to said host a vaccine.

32. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered simultaneously with said vaccine.

33. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered prior to the administration of said vaccine.

34. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered after the administration of said vaccine.

35. The method of claim 31, wherein R' is H-, Glx-, Thr-Ala-Glx-, Thr-Pro-Glx-, Ser-Ala-Glx-, Ser-Pro-Glx-, Ser-Ser-Glx-, Met-Leu-Thr-Ala-Glx-, or Leu-Thr-Ala-Glx-; and R" is -H, -Ala, -Ala-Ala or -Ala-Val.

36. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is selected from the group consisting of: Thr-Ala-Glu-Glu-Lys, Thr-Ala-Gln-Gln-Lys, and Glu-Lys.

37. The method of claim 31, wherein R" is -H.

38. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is selected from the group consisting of: Thr-Pro-Glu-Glu-Lys, Thr-Pro-Gln-Gln-Lys, and Thr-Pro-Glx-Glx-Lys.

39. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is selected from the group consisting of: Leu-Thr-Ala-Glx-Glx-Lys-Ala, Leu-Thr-Ala-Glx-Glx-Lys-Ala-Ala, and Leu-Thr-Ala-Glx-Glx-Lys-Ala-Val.

40. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered as a pharmaceutical composition.

41. The method of claim 40, wherein said pharmaceutical composition comprises said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof in an amount of 0.001% to 20% by weight and a pharmaceutically acceptable carrier.

42. The method of claim 41, wherein said pharmaceutically acceptable carrier is an aqueous solution.

43. The method of claim 41, wherein said pharmaceutically acceptable carrier comprises a buffer selected from sodium acetate, sodium lactate, sodium chloride, potassium chloride and calcium chloride.

44. The method of claim 41, wherein said pharmaceutical composition comprises 0.1 mg of the peptide.

45. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered parenterally.

46. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered orally.

47. The method of claim 31, wherein said peptide having the formula R'-Glx-Lys-R" or a pharmaceutically acceptable salt thereof is administered intranasally, intravenously or intramuscularly.